Comparison of Laser Speckle Contrast Imaging (LSCI) and Laser Doppler Imaging (LDI)

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o To test the linearity of the LSCI device (Perimed AB, Järfälla, Sweden) and LDI device (Moor Instruments, Devon, UK) in a wide range of blood flux valueso To compare arbitrary units of two different kinds of laser-based devices and to create a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45743

Source
ToetsingOnline

Brief title
Comparison of LSCI and LDI
Acronym:LACOM Study= LAser COMpare study

Condition

- Other condition
- Skin vascular abnormalities

Synonym
blood flow of small capillaries and microcirculation

Health condition

microcirculation and tissue perfusion

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: PPI Health Holland

Intervention

Keyword: iontophoresis, Laser doppler imaging, Laser speckle contrast imaging, microcirculation

Outcome measures

Primary outcome

Standard operating procedure for measurement of cutaneous microcirculatory

perfusion: mean blood flux values [LSCI (Perimed AB, Järfälla, Sweden) & LDI

(Devon, UK)]

The study process in one volunteer will be ended once the iontophoresis and

stepwise occlusion completed.

Secondary outcome

na

Study description

Background summary

The microcirculation plays a fundamental role in the human body and it has been shown as an essential determinant in many clinical scenarios such as shock states, chronic and cardiac diseases. Microcirculation can be assessed directly using laser-based techniques and intravital microscopes. When combined with provocation tests, microvascular monitorization can be used to assess microvascular function.

Laser-based techniques are consist of two different methods named laser doppler imaging (LDI), laser speckle contrast imaging (LSCI). LSCI is a technique based on speckle contrast analysis that provides an index of blood flux. No need for

skin contact, continuous and real-time assessment of the microcirculation led the LSCI to be broadly used in clinical practice.
LDI is also a non-invasive diagnostic method used to measure blood flux of tissue. The technique is based on measuring the doppler shift induced by moving red blood cells to the illuminating coherent light. Iontophoresis is one of the most commonly used provocation test to study the endothelium in terms of endothelium-dependent and endothelium-independent vasodilation. Simultaneously with LDI and LSCI are used to follow and assess the skin blood flux during iontophoresis. Therefore, it provides a state to make a comparison between two different laser-based techniques in terms of flux characteristics.

The accurate assessment of burn depth is a critical step in the management of the burn-injured patient. Currently, LDI is the most widely used noninvasive measurement tool for the assessment of burn wounds and the only technique that has been approved by the U.S. Food and Drug Administration. However, LDI device is rather costly, cumbersome and has a poor spatial resolution. LSCI measures perfusion in a similar way, but it provides high quality images with a much higher spatial resolution. In addition, LSCI is much quicker, maneuverable and able to assess more larger skin areas. In order to use LSCI technique in clinical practice of burn-injured patients, as a first step, linearity of LDI and LSCI should be shown. In this study we aimed to compare LSCI and LDI with iontophoresis and stepwise occlusion technique. So, we will be able to test the linearity of devices over a large range of blood flux values.

Study objective

o To test the linearity of the LSCI device (Perimed AB, Järfälla, Sweden) and LDI device (Moor Instruments, Devon, UK) in a wide range of blood flux values
o To compare arbitrary units of two different kinds of laser-based devices and to create a common and universal unit
o To create a color code, comparing LDI and LSCI

Study design

Single-center, prospective, observational and non-interventional study in the Maastad Hospital, Rotterdam, The Netherlands

Study burden and risks

Microcirculation assessment is a non-invasive procedure, and there are no risks associated with LSCI and LDI devices. Additional blood tests are not required. The risks can be considered negligible, and the burden can be considered minimal. Major side-effects are rare with using iontophoresis. However, minor reactions such as itching, erythema and general irritation of the iontophoresis skin surface are common during procedure. Discoloration of the skin may occur.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
Healthy human volunteers older than 18 years who conform to following criteria:
* Should not have any disease at the time of procedure (including flu)
* Should not have any chronic disease
* Should not be under any medication
* Should not be smoker or ex-smoker
* Should not drink coffee or eat the meal in two hours before the procedure
* Should not have an allergy to sodium-nitroprusside

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:;* The volunteer who does not meet any of the criteria above
* <18 years old
* Pregnant
* Refusal to participate in the study or demand to end study for any reason
* Hypersensitivity/allergy to sodium nitroprusside
* Broken or damaged skin surfaces
* Electrically-sensitive implanted devices such as cardiac pacemakers
* Maastad Ziekenhuis employees or collegues

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2018
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	16-11-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL65747.101.18